DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: BAYTRIL®
Docket No. 96E-0504

MAR 10 1997

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,670,444, filed by Bayer Aktiengesellschaft, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for BAYTRIL®, the animal drug product claimed by the patent.

The total length of the review period for BAYTRIL® is 4,334 days. Of this time, 648 days occurred during the testing phase and 3,686 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 512(j) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: November 24, 1984.

   The applicant claims November 20, 1984 as the date the Investigational New Animal Drug application (INAD) became effective. However, FDA records indicate that the date of FDA's official acknowledgment letter assigning a number to the INAD was November 24, 1984, which is considered to be the effective date for the INAD.

2. The date the application was initially submitted with respect to the animal drug product under subsection 512(b) of the Federal Food, Drug, and Cosmetic Act: September 2, 1986.

   The applicant claims August 26, 1986, as the date the New Animal Drug Application (NADA) for BAYTRIL® (NADA 140-828) was initially submitted. However, a review of FDA records reveals that the date of FDA's official acknowledgement letter assigning a number to the NADA was September 2, 1986, which is considered to be the initially submitted date for the NADA.

3. The date the application was approved: October 4, 1996.

FDA has verified the applicant's claim that NADA 140-828 was approved on October 4, 1996.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Kurt G. Briscoe
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